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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,088	02/02/2004	Chin-Chih Chiang	OEP2003-01	9267
26709	7590	05/30/2006	EXAMINER	
SHIHONG NICOLAOU 4931 ARROYO LINDO AVE. SAN DIEGO, CA 92117			AHMED, HASAN SYED	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/770,088	CHIANG, CHIN-CHIH	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/2/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Receipt is acknowledged of the application, including IDS, filed on 2 February 2004.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Taiwan on 10 September 2003. It is noted, however, that applicant has not filed a certified copy of the Taiwanese application as required by 35 U.S.C. 119(b).

Specification

The use of the trademarks PEMULEN TR-1NF, CARBOPOL ETD 2020 and CARBOMER has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Ebert, et. al. (U.S. 2003/0147926 A1).

Ebert, et. al. teach a topical gel formulation of oxybutynin (see paragraph 0012) as well as a method for treating bladder disorders using said topical gel (see paragraph 0017).

The disclosed formulation is the instant formulation as claimed (see example 10):

- 2.2 wt. % oxybutynin chloride salt;
- 58.8 wt. % of a short chain alcohol; and
- 2.0 wt % of a gelling agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert, et. al.

Ebert, et. al. teach a topical gel formulation of oxybutynin as well as a method for treating bladder disorders using said topical gel (see above).

The disclosed formulation is comprised of 2.2 wt. % oxybutynin chloride salt; 58.8 wt. % of a short chain alcohol; and 2.0 wt % of a gelling agent (see example 10).

Although the Ebert, et. al. reference does not provide an example of a formulation with all excipients claimed by applicant, it teaches every excipient claimed:

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- the short chain alcohols of instant claim 2, i.e., ethanol and isopropanol (see paragraph 0122);
- the gelling agents of instant claims 3 and 4, i.e., CARBOPOL, CARBOMER and PEMULEN (see paragraph 0116);
- the permeation enhancers of instant claims 6 and 7, i.e., *inter alia*, isopropyl myristate (see paragraph 0134);
- the concentration of permeation enhancer of claim 5, i.e. 5.0 wt % (see example 10);
- the moisturizer of instant claims 8 and 9, i.e., propylene glycol (see paragraph 0127); and
- the method for treating bladder disorders of instant claim 10 (see paragraph 0017).

Ebert, et. al. explain that combining the disclosed agents into a topical gel formulation is beneficial because it mitigates the adverse drug effects associated with oxybutynin therapy (paragraphs 0006 and 0007).

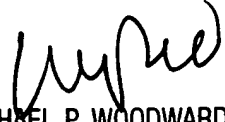
It would have been obvious to a person having ordinary skill in the art at the time of the invention to make a topical gel formulation of oxybutynin (comprising a short chain alcohol, a gelling agent a permeation enhancer and a moisturizer) to treat bladder disorders. Motivation would come from mitigation of adverse drug effects associated with oxybutynin therapy, as taught by Ebert, et. al., as discussed above. Those of ordinary skill in the art would expect similar properties from the instant formulation, given the teachings of Ebert, et. al.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
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